IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Kalpana Kamath et al.	Art Unit	: 1793
Serial No.	: 10/814,079	Examiner	: Pegah Parvini
Filed	: March 30, 2004	Conf. No.	: 5482
Title	: EMBOLIZATION		

Commissioner for Patents
P.O. Box 1450
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REPLY BRIEF

Pursuant to 37 C.F.R. § 41.41, Appellant responds to the Examiner's Answer as follows.

The Examiner is Improperly Relying on Non-Analogous Art

As explained in the M.P.E.P., for an Examiner to rely on a reference under 35 U.S.C. §103, the reference must be analogous art. *See* M.P.E.P. §2141.01(a). As explained by the United States Court of Appeals for the Federal Circuit, "[t]he analogous art test requires that the Board show that a reference is either in the field of the applicant's endeavor or is reasonably pertinent to the problem with which the inventor was concerned in order to rely on that reference as a basis for rejection." *See In re Kahn*, 441 F.3d 977, 986-87 (Fed. Cir. 2006), quoting *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992).

Appellant believes that Chevallier is neither in the field of Appellant's endeavor nor reasonably pertinent to the problem with which Appellant was concerned.

Appellant's field of endeavor is compositions appropriate for use in embolization procedures. *See, e.g.,* U.S.S.N. 10/814,079, p. 1, lines 2-10; p. 3, line 23-p. 7, line 28; and Figs. 1A, 1B and 2. The problem with which Appellant was concerned was, for example, providing such compositions that could enhance the suspendability of the particles in a delivery medium such as a contrast agent, while having a relatively small pore size to enhance surface uniformity, robustness and abrasion resistance. *See, e.g., id.*, p. 3, lines 1-6. The problem with which Appellant was concerned was, as a further example, providing such compositions in which the particles had pore volume selected to contain a desired therapeutic agent volume, and pore size

can be selected to produce a desired time release, based on diffusion of therapeutic agent from the pores. *See, e.g., id.*, lines 6-10.

In stark contrast, Chevallier discloses precipitated particles designed for use as a reinforcing filler in elastomers. *See, e.g.,* Chevallier, Abstract. Chevallier has nothing whatsoever to do with embolization. Thus, Chevallier is not within the field of Appellant's endeavor, and Chevallier is not reasonably pertinent to the problem with which Appellant was concerned.

Also in stark contrast, Kirkland discloses particles designed to serve as scavengers in a reaction mixture by binding to excess reactants and reactant by-products in the reaction mixture. *See, e.g.,* Kirkland, Abstract. Kirkland also has nothing whatsoever to do with embolization. Thus, Kirkland also is not within the field of Appellant's endeavor, and Kirkland also is not reasonably pertinent to the problem with which Appellant was concerned.

Chevallier is not analogous art, and Kirkland it not analogous art. It is therefore improper for the Examiner to rely on either Chevallier or Kirkland in rejecting the claims. The situation is even more extreme considering that the Examiner uses Chevallier and Kirkland as primary references in rejecting the claims.

In view of the foregoing, the rejections of the claims should be reversed.

The Examiner Failed to Establish Inherent Disclosure in Mangin and Chevallier

It is Appellant's position that the Examiner has not established that either Mangin or Chevallier inherently disclose particles having a pore volume distribution such that about 70% or more of the pore volume of the particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore diameter, as required by claims 4-8, 11-13, 24 and 25. *See, e.g.,* Appeal Brief, pp. 4-7. Now, for the first time, and despite Appellant's repeatedly making the inherency argument, the Examiner has introduced new arguments to try to establish inherency. *See* Examiner's Answer, p. 18. But, the Examiner's argument is insufficient to establish that either Mangin or Chevallier inherently disclose the subject matter noted above.

Appellant notes that the MPEP itself establishes the burden for the Examiner to establish that the allegedly inherent property "necessarily flows" from the disclosure in the references relied upon by the Examiner. *See, e.g.,* MPEP §2112, citing *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) ("In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.") (emphasis in original). It simply is not enough that the a property alleged to be inherently disclosed "is expected to follow" (*see* Examiner's Answer, p. 18). *See* MPEP §2112 ("The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.") (emphasis in original).

Instead of complying with the legal standard, the Examiner asserts that, because of an alleged overlap in the ranges of particle diameter disclosed in prior art and covered by the claims (which Appellant does not concede is an accurate interpretation of the subject matter disclosed in the prior art and/or the subject matter covered by the claims), the prior art inherently discloses particles having a pore volume distribution such that about 70% or more of the pore volume of the particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore diameter. *See* Examiner's Answer, p. 18. This allegation would be insufficient to establish inherent disclosure, even if there were complete overlap in the ranges of particle diameter, at least because the Examiner provides absolutely no basis (let alone any evidence of record, *see* MPEP § 2144.03) for linking diameter with the claimed properties alleged to be inherently disclosed in the prior art. But, where there isn't even complete overlap in the ranges, the Examiner's argument can by no stretch of the imagination be used to establish the alleged inherent disclosure.

The Examiner also refers to the table at column 10 of Chevallier to support the Examiner's argument regarding inherency. *See* Examiner's Answer, p. 18. Appellant does not see how this portion of Chevallier's disclosure helps the Examiner's argument. As Appellant reads this table, it indicates that there was a total pore volume of 3.11cm^3/g, but that only 0.46 cm^3/g of the pore volume was in the range of 175 angstroms to 275 angstroms. *See* Chevallier,

col. 10, lines 38-53. Based on this, Appellant believes that less than 15% of the pores were in the range of 175 angstroms to 275 angstroms. Accordingly, Appellant believes that the Examiner's reliance on pores in this range does not mean that the particles noted in the table of column 10 of Chevallier inherently have a pore volume distribution such that about 70% or more of the pore volume of the particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore diameter.

As a result, the Examiner has not established that Mangin or Chevallier inherently disclose particles having a pore volume distribution such that about 70% or more of the pore volume of the particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore diameter, as required by claims 4-8, 11-13, 24 and 25.

In view of the foregoing, the rejection of these claims based on the combination of Mangin and Chevallier should be reversed.

The Examiner Failed to Establish Inherent Disclosure in Mangin and Kirkland

Further, it is Appellant's position that neither Mangin nor Kirkland inherently disclose particles having a pore volume distribution such that about 70% or more of the pore volume of the particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore diameter, as required by claims 4-8, 11-13, 24 and 25. *See, e.g.,* Appeal Brief, pp. 8-9. Here again, however, the Examiner introduces a new argument to try to establish inherent disclosure. With regard to Kirkland, the Examiner again trots out the "is expected to follow" argument, which, as noted above, does not comply with the legal standard. *See id.*, p. 19. Further, the Examiner (without any evidentiary support) somehow concludes that an alleged overlap in ranges of porosity, size and density of Kirkland's particles and Appellant's claimed particles means that Kirkland's particles inherently have a pore volume distribution such that about 70% or more of the pore volume of the particles is made up of pores having pore diameters which have a tolerance of about 10 nm or less on the mean pore diameter. Of course, such a conclusory and unsupported assertion is condemned by the MPEP. *See* MPEP § 2144.03. The

fact is, the Examiner's alleged connection between the above-noted variables is without merit, and should not be considered as establishing the requisite inherent disclosure.

The Examiner also cites to *Spada*, *Fitzgerald* and *Swinehart* to try to support his position. *See* Examiner's Answer, pp. 19-20. Appellant explained why these case are not helpful to the Examiner in the Appeal Brief at page 7.

In view of the foregoing, Appellant against requests reconsideration and reversal of the rejections of the pending claims.

Appellant believes no fee is due. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: February 19, 2010

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